UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION **THIS DOCUMENT RELATES TO:** **All Direct Purchaser Actions**	**Case No. 1:15-cv-07488-CM-RWL**

PLAINTIFFS' OPPOSITION TO FOREST'S MOTION *IN LIMINE* NO. 9 TO PRECLUDE EVIDENCE OF "SPECULATIVE LESS RESTRICTIVE ALTERNATIVES"

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I. INTRODUCTION

Forest's Motion *in Limine* No. 9 is based on a serious misconception. Forest argues that Plaintiffs' assertion that the Lexapro Amendment contained a large reverse payment from Forest to Mylan is governed by the "less restrictive means" test of the Rule of Reason's third prong. Defs.' Br. at 1 ("DPPs apparently intend for their experts to opine that there were less restrictive alternatives by which Forest could have achieved the benefits that resulted from the Lexapro Amendment") (ECF No. 779). That is incorrect. Plaintiffs offer the evidence to which Forest refers (it cites just six paragraphs from three expert reports and attaches a few pages of those reports as exhibits) to show that Forest effectuated a large reverse payment by overpaying Mylan through the Lexapro Amendment, because Forest could have gotten the same benefit for far less money, and to rebut Forest's argument that its payments were for fair value. In other words, Plaintiffs offer this evidence to show that Forest's $32.5 million payment to Mylan was large and had anticompetitive effects. Contrary to Forest's assertions, the less restrictive means analysis of the rule of reason's third prong is whether any cognizable procompetitive benefits a defendant identifies can be accomplished in a less restrictive manner. Here, the challenged restraint was the delay of competition for Namenda, not Lexapro. Assuming a jury even reaches the third prong of the rule of reason (it would first have to conclude that Forest offered a cognizable procompetitive justification for paying Mylan to delay its generic Namenda IR launch), the issue it would ultimately have to consider is whether, weighing all the evidence, generic Namenda entry could have taken place earlier had Forest not made a reverse payment.

It is perfectly clear that Plaintiffs do not offer this evidence as a less restrictive means response to Forest's purported procompetitive justification for the challenged restraint for the following reasons. *First*, Forest applies the third prong of the rule of reason to the wrong agreement. Plaintiffs have challenged the Namenda patent litigation settlement, which included

a large reverse payment embedded in the compensation terms of the Lexapro Amendment, as an unlawful reverse payment agreement that delayed generic competition in the market for memantine hydrochloride; they have not alleged that the Lexapro Amendment was an independent unlawful restraint of trade in the Lexapro market. Thus, Plaintiffs have no burden to show that any procompetitive effects of the Lexapro Amendment (assuming there were any) could have been achieved through less restrictive alternatives. Further, the law is clear that the Lexapro Amendment's benefits to consumers (of which Forest has adduced zero proof, and points to none in its motion) cannot serve as a cognizable procompetitive justification for the restraint of memantine hydrochloride competition challenged in this case, because Lexapro and memantine hydrochloride are not in the same market. This Court has ruled that the relevant market in this case is limited to memantine hydrochloride, and Forest never argued that Lexapro should have been included. Thus, Forest's misdirection – focusing on whether the Lexapro Amendment could have been achieved by a less restrictive means – is contrary to the governing rule of reason framework. The issue regarding the Lexapro Amendment is whether it was for fair value (which Forest has the burden to prove under *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013)), not whether the Lexapro Amendment constrained Lexapro competition.

Second, the third prong of the rule of reason that Forest attempts to invoke would apply in this case only after Forest has satisfied its burden under the second prong and demonstrated a procompetitive benefit from the challenged restraint – here the reverse payment and delayed generic competition in the market for memantine hydrochloride. It is the reverse payment and delay that require justification. *Actavis*, 570 U.S. at 156 ("An antitrust defendant may . . . explain[] the presence of the *challenged term* and show[] the lawfulness of *that term* under the rule of reason.") (emphasis added); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir.

2012), *vacated on other grounds*, 570 U.S. 913 (2013) (a "reverse payment [must] offer[] a competitive benefit."). There is absolutely no evidence anywhere in the record, however, of any cognizable procompetitive benefit flowing from the reverse payment agreement. Thus Forest has not satisfied its burden for the third prong to be applied.

Third, even if the question whether there were procompetitive benefits flowing from the Lexapro Amendment were somehow relevant to this case, neither Forest's contentions, nor its proposed verdict form and jury instructions, identifies any alleged benefits of the Lexapro Amendment that Forest will assert as a purported procompetitive justification for the challenged restraint on memantine hydrochloride competition in this case. *See* ECF 699-2 (Forest's contentions, no mention of procompetitive justifications at all, much less from the Lexapro Amendment); ECF 704-1 at Question 5 (proposed verdict form); ECF 704-2 at Instruction 40 (proposed jury instructions). Thus, even if it could do so under controlling law, and even if it could have its experts at this late date construct some new theory of how the consumer benefits of the Lexapro Amendment necessitated the restraint on memantine hydrochloride competition challenged in this case (which would require wholly new expert reports), Forest's pretrial submissions clearly abandon such an argument, and take with them the major premise of its motion.

Forest's motion should be denied.

II. FACTS

Plaintiffs will prove at trial that Forest's reverse payment in the Namenda patent settlement was conveyed to Mylan through an amendment to a prior marketing agreement covering the authorized generic version of the antidepressant Lexapro ("Lexapro AG"). As the Court knows, on August 3, 2005, Forest signed the first of two agreements with Mylan and/or its

predecessor, Alphapharm. Under it, Alphapharm would sell an authorized generic version of Lexapro but would pay 40% of its profits to Forest. Pls.' Contentions, ECF No. 699-1 at ¶ 128.

Then, on the same date that Forest and Mylan signed the Namenda patent settlement agreement (July 21, 2010), Forest and Mylan signed an amendment to the original Lexapro deal (the "Lexapro Amendment"), which lowered Mylan's royalty obligation from 40% to 30% on the first $100 million in profits and from 40% to 35% on the next $50 million in profit. *Id*. at ¶ 129. The Lexapro Amendment effectively diminished the royalties Mylan owed Forest by $12.5 million. Forest also agreed to pay Mylan an immediate $20 million lump sum, for a total payment of $32.5 million. *Id*.

The Lexapro Amendment was linked directly to the Namenda patent settlement. *See id*. at ¶¶ 136-37 (citing evidence).

In his report, Plaintiffs' manufacturing expert Mr. Bruno, who has forty-five years of experience in pharmaceutical manufacturing, including negotiating supply deals, demonstrated, among other things, that Forest grossly overpaid for the manufacturing responsibilities Mylan assumed under the Lexapro Amendment. Specifically, he explained that the $32.5 million in compensation that Forest was to provide to Mylan was at least $30.9 million more than the rightful cost of the manufacturing services Mylan was retained to perform. Declaration of Joseph Opper ("Opper Decl.") Ex. 19, Expert Report of James Bruno at *e.g.*, ¶¶ 21, 42, 102-103. The thrust of Mr. Bruno's opinion is that the Lexapro Amendment was not for fair value. To support his opinion, he opines, among many other things, that another entity, such as a contract manufacturing organization, could make Lexapro AG at a much lower cost. *Id*. at ¶¶ 73-74. Forest ignores Mr. Bruno's opinion concerning the availability of contract manufacturing organizations and instead complains that Mr. Bruno's opinion concerning contracting with

generic manufacturers other than Mylan is speculative (Defs.' Br. at 4), but Forest cannot dispute that there were over a dozen manufacturers that were actually marketing generic Lexapro after Teva's 180-day exclusivity period. Pls' Contentions, ECF No. 699-1 at ¶¶ 151-52.

Prof. Elhauge likewise explains from an economics perspective that Forest's position that "Forest would receive $0 in profits on its authorized generic if Mylan terminated" was "economically irrational." Specifically, assuming arguendo that Forest really did think there was significant money to be made in year-two of selling an authorized generic, then "[i]f Mylan terminated, Forest would have every incentive to either sell an authorized generic itself or engage another firm to sell Lexapro as an authorized generic." Toto Decl. Ex. 3, ECF No. 780-3 (excerpt from Elhauge Report). Thus, as Prof. Elhauge opines, simple economics shows that Forest's purported second-year royalty defense (*i.e.*, that Forest had to pay Mylan to keep it from terminating after one year) does not "explain and [] justify" the reverse payment to restrain competition in the memantine hydrochloride market as "one who makes such a payment" must do. *Actavis*, 570 U.S. at 158.

III. ARGUMENT

A. Controlling Rule of Reason Law

Under the *Actavis* framework as interpreted by other courts applying it to a rule of reason analysis, a plaintiff is required to show that a patentee made a large reverse payment to induce its generic challenger to quit the patent fight and delay entering the market. If the plaintiff shows a large reverse payment and market power, a jury can find it has established an anticompetitive restraint of trade. *E.g.*, *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 422 (E.D. Pa. 2015) ("For the reasons stated above, I find that a plaintiff challenging a reverse-payment settlement as anticompetitive under *Actavis* must demonstrate anticompetitive effects, including a large reverse payment, under the first step of the rule of reason.").

As in any rule of reason antitrust case, the burden then shifts to the defendant to explain the restraint or otherwise offer a cognizable procompetitive justification for it. The defendant can explain the transaction by proving that the reverse payment represented "fair value for services" the generic performed for the brand (*i.e.*, it was for something other than delay). *See Actavis*, 520 U.S. at 156 ("The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform — such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present."); *id*. at 158 ("one who makes such a payment may be unable to explain and to justify it.").

Cognizable procompetitive benefits for a restraint that a defendant can offer are those that lower consumer prices, expand output, increase product quality, or increase consumer choice. Thus, benefits to the defendant itself (such as saving money) are not cognizable. *See* Pls.' Mot. *in Limine* No. 6 at 4-6 (ECF No. 744) (benefits enjoyed by businesses or competitors are not cognizable procompetitive justifications); *McWane, Inc. v. FTC*, 783 F.3d 814, 841 (11th Cir. 2015) ("cognizable justifications are typically those that reduce cost, increase output or improve product quality"). To be cognizable, such competitive benefits must also be experienced in the same market as the challenged restraint (here, the memantine hydrochloride market). *See United States v. Topco Assocs.*, 405 U.S. 596, 610 (1972) ("[Competition] cannot be foreclosed with

respect to one sector of the economy because certain private citizens or groups believe that such foreclosure might promote greater competition in a more important sector of the economy.") (citation omitted); *Sullivan v. NFL*, 34 F.3d 1091, 1112 (1st Cir. 1994) ("improper to validate a practice that is decidedly in restraint of trade simply because the practice produces some unrelated benefits to competition in another market"); *Clarett v. Nat'l Football League*, 306 F. Supp. 2d 379, 409 (S.D.N.Y. 2004) (defendant "may not justify the anticompetitive effects of a [restraint] by arguing that it has procompetitive effects in a different market").

Finally, and only ***if*** the defendant offers and proves a cognizable procompetitive justification, then the plaintiff has an opportunity to show that the procompetitive goal could have been achieved through means less restrictive of competition than the challenged restraint, or alternatively, that the procompetitive benefits are outweighed by the anticompetitive effects (here, the reverse payment and associated delay of Namenda competition). *See In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 198 (S.D.N.Y. 2018) ("***If*** defendant is able to offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives."), citing *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 104 (2d Cir. 2010) (quotation omitted) (emphasis added); *New York v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015) (under the third prong, "[t]he plaintiff may . . . either rebut [defendants'] justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit."). The focus of the "less restrictive means" analysis, if a defendant's proof allows it to be reached at all, is the necessity of the challenged anticompetitive restraint: was the challenged restraint (here, Forest's reverse payment and Mylan's delayed generic Namenda launch) necessary to achieve Forest's asserted procompetitive justification, or were there other means less restrictive than the

challenged restraint that would achieve those procompetitive benefits. *See NASL v. NFL*, 670 F.2d 1249, 1261 (2d Cir. 1982) (defendant NFL had failed to prove the "market necessity" of its restraint — a ban on team owners also owning soccer teams — and "was required to come forward with proof that any legitimate purpose could not be achieved through less restrictive means.").

Ultimately, the jury will weigh the anticompetitive restraint against any cognizable procompetitive justifications, and if the anticompetitive restraint on balance is greater than the procompetitive justifications, the jury can find the conduct violated the Sherman Act.

B. Forest Never Offered a Cognizable Procompetitive Benefit, So Plaintiffs Never Had to Demonstrate Less Restrictive Means

Here, Plaintiffs have challenged the Namenda pay-for-delay deal, contending that Forest paid Mylan $32.5 million to stay off the market until 3 months prior to patent expiry. In its defense, Forest has asserted that the $32.5 million it paid Mylan (via the Lexapro Amendment) was not a payment to delay generic competition in the market for memantine hydrochloride, but instead was an independent, arm's-length deal for "fair value" relating to generic Lexapro and thus there was no reverse payment from Forest to Mylan. But Forest has never asserted that its reverse payment to Mylan and Mylan's delay lowered memantine hydrochloride prices, or increased memantine hydrochloride output, choice, or quality, which are the universe of cognizable procompetitive justifications available to it. *McWane, Inc.* 783 F.3d at 841. It has instead made other (impermissible) arguments about risk aversion and so-called "early" entry that are the subject of Plaintiffs' Mot. *in Limine* No. 6 (ECF No. 744). Forest has also made the equally-impermissible argument that it saved on Medicaid rebates for a drug in another market, Lexapro. *See Clarett*, 306 F. Supp. 2d at 409 ("desire to keep [] costs down is not a legitimate procompetitive justification."). Significantly, Forest has never identified the Lexapro

Amendment as a procompetitive justification for, what Plaintiffs will prove was an agreement to delay Namenda competition.

Forest has never asserted, through an expert or otherwise, that any purported procompetitive benefits of the Lexapro Amendment necessitated a reverse payment from Forest to Mylan or Mylan's delay of generic Namenda IR competition. In its pretrial submissions, Forest mentions none of these things and therefore abandons all of them. Even if one could get past the simple fact that any alleged consumer benefits of the Lexapro Amendment (which Forest has never identified) would be experienced in a market different from the market for memantine hydrochloride, it is difficult to even conceive of a theory under which Forest's reverse payment and Mylan's delayed generic Namenda IR entry would be necessary to achieve consumer benefits involving Lexapro.

The cases Forest cites provide no support for its position that the rule of reason analysis, and the least restrictive means portion of that analysis, should be applied to the Lexapro Amendment. In Forest's cases, the question is whether a means less restrictive than the ***challenged restraint*** could achieve the asserted procompetitive benefit. *See N. Am. Soccer League, LLC v. United States Soccer Fed'n,* 883 F.3d 32, 45 (2d Cir. 2018) (less restrictive means analysis applied to challenged league standards and not to a side agreement); *O'Bannon v. Nat'l Coll. Athletic Ass'n,*, 802 F.3d 1049, 1074 (9th Cir. 2015) (less restrictive alternative means analysis applied to challenged NCAA rules barring student-athlete compensation at issue in case).

C. The Bruno and Elhauge Reports Are Appropriate Expert Opinions Grounded in Fact

In what amounts to a belated *Daubert* motion, Forest takes issue with three opinions from the Bruno and Elhauge reports that it never previously challenged (Forest previously tried and

largely failed to disqualify Prof. Elhauge on other grounds). The Court should not consider this belated argument. Under the Third Amended Case Management Order, *Daubert* challenges to expert testimony were due on November 17, 2017. ECF No. 397 at 2. Forest's present motion argues that certain of Prof. Elhauge and Mr. Bruno's opinions should be excluded under *Daubert/Kumho Tire* as part of the Court's "gatekeeping" function. It is too late for that. *Hart v. BHH, LLC*, No. 15cv4804, 2019 U.S. Dist. LEXIS 58474, at *2-3 (S.D.N.Y. Apr. 4, 2019) ("But these are classic *Daubert* questions which could have been raised in the first *Daubert* motion. Accordingly, this Court construes Defendants' second motion *in limine* as an untimely *Daubert* motion in violation of this Court's scheduling order or as an untimely motion for reconsideration."). As this Court has explained:

> As far as this court is concerned, the Parties have waived any *Daubert* arguments by not raising them at summary judgment. ***If I can consider an expert's [testimony] at summary judgment, a jury can consider it at trial***.

United States v. Teva Pharm. USA, Inc., 13 Civ. 3702, 2019 U.S. Dist. LEXIS 35148, at *37 (S.D.N.Y. Feb. 27, 2019) (McMahon, J.) (emphasis added).

Even if the Court proceeded to allow Forest its impermissible re-do, it would find that all three opinions are appropriate expert opinion testimony that derive from the facts at issue in this case together with the expert's experience and expertise in their subject area.

Defendants attack Mr. Bruno for his opinion that using Mylan to manufacture Lexapro AG resulted in no API savings for Forest. Specifically Forest contends that Mylan was required to use API manufactured by Lundbeck, which produced expensive API, instead of a cheaper alternative. But it is counterfactual that Mylan was required by "contractual commitments" (Defs.' Br. at 5) to use API from Lundbeck – indeed Forest fails to inform the Court that less than two weeks after executing the Lexapro Amendment, Lundbeck released Forest from the

obligation that Mylan use Lundbeck's API. Opper Decl. Ex. 20, PX-1022 at FRX-AT-0428193. Moreover, Mr. Bruno identified that in addition to Mylan, "a number of Indian generic pharmaceutical companies submitted [Drug Master Files] covering the manufacturing of Escitalopram API around the same time as Mylan," and cited his sources. Opper Decl. Ex. 19, Bruno Rpt. at ¶ 40. While Mylan used Lundbeck's API anyway (Opper Decl. Ex. 21, PX-1019 at FRX-AT-4621811 at -812), that does not mean that Mr. Bruno's opinion was speculative. In fact, the evidence shows that at the time, there were even cheaper sources of API that were offered to Forest from third-parties. Opper Decl. Ex. 22 at FRX-AT-04617638 at -638.

Mr. Bruno's opinion is not speculative, but is rooted in his understanding of pharmaceutical manufacturing and the record.

Forest also misconstrues Mr. Bruno's opinions concerning Forest's purported Medicaid rebate savings. In particular, Mr. Bruno opined, based on his forty-five years of experience in pharmaceutical manufacturing, including specifically in negotiating supply deals (Opper Decl. Ex. 19, Bruno Rpt. at ¶¶ 5-10), that Forest's Medicaid savings are not properly considered in valuing the manufacturing services Mylan promised to perform under the Lexapro Amendment, because Forest's unilateral Medicaid savings are extraneous to any of those services (*i.e.*, Mylan did not provide them, the government did). *See* Opper Decl., Ex. 23, Bruno Reply Rpt. at ¶ 26. He further opined that even if Forest's Medicaid rebate savings were properly considered part of the services Mylan performed, the payment from Forest to Mylan under the Lexapro Amendment surpassed Forest's Medicaid rebate savings, indicating that the Lexapro Amendment was not an arm's-length deal for Forest. *Id*. at ¶¶ 27-28.

Finally, Forest takes issue with Mr. Bruno and Prof. Elhauge's explanations that rebutted Forest's expert Philip Green. Both experts explained, based on their reading of the agreements

coupled with their expertise in the pharmaceutical area, the options available to Forest if Mylan had elected to terminate the original Lexapro agreement after the first year. Mr. Bruno opined that Mr. Green adduced no evidence that Mylan was likely to terminate after one year and that in fact, it would not make sense for Mylan to do so because Mylan could not replace the income it was making selling Lexapro AG (under Forest's NDA) with its own generic Lexapro because Mylan never attained FDA final approval to make its own generic Lexapro. Opper Decl. Ex. 23, Bruno Reply Rpt. ¶¶ 13-15, 18, 20. He also opined that even if Mylan opted to sell its own ANDA generic Lexapro royalty-free despite not having FDA approval to do so, Forest could have replaced it. *Id*. at ¶ 16. Prof. Elhauge opined that, assuming arguendo that Forest's assumptions were correct that there was any money to be made in a second year of Lexapro AG sales, Forest was free to manufacture its own authorized generic if Mylan opted out. Toto Decl. Ex. 3, ECF No. 780-3, (excerpt from Elhauge Report) at ¶¶ 19-20. Prof. Elhauge explained from an economics perspective that under ***Mr. Green's assumptions***, it would have been "economically irrational" for Forest not to sell its own AG "given that Forest could make tens of millions of dollars by selling an authorized generic." *Id*. None of these statements is speculative or in any way impermissible. Prof. Elhauge also opined, assuming *arguendo* that the assumptions in Forest's documents were correct that Mylan in fact could manufacture Lexapro AG less expensively than Forest could, rational economic actors would enter into the Lexapro Amendment even without Forest's $32.5 million payment to Mylan because both Forest and Mylan would split any cost savings under that deal's profit sharing arrangement. Pls.' Affirmative Statement of Facts in Opp'n to Forest's Mot. for Summ. J., ECF No. 613 at ¶¶ 250-51.

These are explanations by experts in the pharmaceutical industry about the options available to Forest based on the agreements that it entered, and the way in which the pharmaceutical industry operates. Moreover, it is obvious that both Mr. Bruno's and Prof. Elhauge's opinions are supported by ample evidence which Forest simply asks the Court to ignore as part of an untimely *Daubert* challenge.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion *in limine* No. 9 should be denied.

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2019, I electronically filed the above by CM/ECF system.

Respectfully submitted,

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